

REMARKS

Claims 11, 17, 19 and 25 have been amended. Claims 16 and 24 have been cancelled. No new matter has been added. In view of the amendments above, claims 11-15, 17-23, 25 and 26 are now pending.

Summary of Presently Presented Claims

Pending claims 11-15, 17 and 18 include a method for detecting or measuring an analyte in a sample by a specific homogeneous binding assay involving three assay ingredients. These ingredients include:

- (a) a haptenylated analyte specific component, which includes a 1st hapten or hapten-like molecule linked to an analyte specific component;
- (b) a 2nd hapten or hapten-like molecule which is not linked to the analyte specific component; and
- (c) an assay component comprising a binding partner which binds to both the 1st hapten or hapten-like molecule (part of ingredient (a)) and the 2nd hapten or hapten-like molecule (ingredient (b)).

The analyte does not interact with the 1st hapten or hapten-like molecule (part of ingredient (a)), the 2nd hapten or hapten-like molecule (ingredient (b)), or the binding partner (part of ingredient (c)). Rather, the analyte can interact with the analyte specific component of ingredient (a) to produce a measurable signal. For ease of reference, these designations of the assay ingredients will be used throughout this response.

In the method covered by claims 11-15, 17 and 18, ingredients (a) and (c) are combined with a sample to form a reaction mixture. The reaction mixture is then incubated, and ingredient (b) is present for at least part of the incubation. This incubation allows the analyte and the analyte specific component of ingredient (a) to interact, producing a measurable signal that is representative of the presence or concentration of the analyte.

Pending claims 19-23, 25 and 26 include a method to improve the sensitivity or precision of a specific binding assay. The method includes providing ingredient (b) and incubating ingredients (a) and (c) with a sample, where ingredient (b) is present for at least part of the incubation. Ingredients (a), (b) and (c) are as described for claims 11-15, 17 and 18.

Rejections under 35 USC § 112

Claims 11-26 were rejected under 35 USC § 112, second paragraph, as being indefinite in the use of the phrase "or the like" in the claims. Applicants would like to thank Examiner Davis for the helpful telephone discussion with Applicants' representative on April 3, 2003. During this discussion, it was noted that the phrase "or the like" does not appear in the pending claims, and that this rejection was directed to the term "haptten-like." The Examiner and Applicants' representative are in agreement that the term "haptten-like" is definite as used in the specification and in this area of research in general. Thus, it has been agreed that this portion of the rejection under 35 USC § 112, second paragraph will be withdrawn.

Claim 11 was rejected under 35 USC § 112, second paragraph, as being unclear as to whether a binding complex is formed with the analyte and as to which assay ingredients would be involved in such a binding complex. Claim 11 was also rejected as being vague and indefinite in the use of the phrase “measuring a signal.” These rejections have been obviated by appropriate amendment. As amended, independent claim 11 now recites the interactions between the homogeneous assay ingredients as:

...

- (d) combining the haptenylated analyte specific component, the sample and the assay component to form a reaction mixture;
- (e) incubating the reaction mixture, such that the interaction of the analyte and haptenylated analyte specific component generates a signal, wherein the second hapten or hapten-like molecule is present for at least part of the incubation; ...

The signal generated by the interaction of the analyte and the analyte specific component (part of ingredient (a) and linked to the 1st hapten or hapten-like molecule) is measured as an indication of the presence or concentration of the analyte. The typical interactions of homogeneous assay ingredients and the measurement of these interactions are described in the specification, for example page 8, line 28 through page 11, line 2, and in Examples 1-3. Thus, amended claim 11 clearly specifies the interaction of the analyte with the ingredients of the assay.

Claims 12 and 22 were rejected under 35 USC § 112, second paragraph, as being unclear as to the meaning of the term “analyte specific component.” This

rejection is respectfully traversed. The term "analyte specific component" is clearly defined in claims 11 and 19 by the recitation of "a haptenylated analyte specific component comprising a first hapten or hapten-like molecule linked to an analyte specific component" (emphasis added). Thus, claims 12 and 22 further define the analyte specific component, which is part of the haptenylated analyte specific component (ingredient (a)).

In view of the amendment and remarks presented above, Applicants assert that all of the presently presented claims fully meet the requirements of 35 U.S.C. § 112, 2nd paragraph and request that these rejections be withdrawn.

Rejections under 35 USC § 102

Claims 11-15, 17-19, 21-23, 25 and 26 were rejected under 35 USC § 102(b) as anticipated by Hevey et al. (U.S. Patent No. 4,228,237). The Examiner asserted that Hevey et al. discloses a competitive binding process which uses a specific binding substance for a ligand, and reagents that include a ligand labeled with biotin and an enzyme labeled with avidin.

The rejection of the claims under 35 U.S.C. § 102(b), including the Examiner's correlation of elements of Hevey et al. with the ingredients of the pending claims, is respectfully traversed. The applied reference fails to provide each and every element of the claims. In particular, the reference does not teach or suggest Applicants' ingredient (c); that is, an assay component comprising a binding partner that binds both the 1st hapten or hapten-like molecule and the 2nd hapten or hapten-like molecule without interacting with the analyte. Rather, Hevey

et al. discloses a conventional sandwich assay in which the analyte (described as a ligand in the reference) is bound between an immobilized specific binding substance and a specific binding substance linked to biotin [col. 2, lines 45-57]. Neither of these sandwich components is equivalent to Applicants' ingredient (c), since they specifically bind to the analyte. The third component of the assay of Hevey et al. is an enzyme labeled with avidin, which can bind to the biotin and allow for detection of the sandwich complex. This component likewise is not equivalent to Applicants' ingredient (c), since it binds only one hapten or hapten-like molecule (i.e. the biotin linked to a specific binding substance) and not a 2nd hapten or hapten-like molecule that is not linked to an analyte specific component.

As noted above in the Summary section, independent claim 11 includes a method involving three assay ingredient (c). Independent claim 19 likewise includes assay ingredient (c) in the incubation step. Hevey et al. cannot anticipate independent claims 11 and 19 since it does not teach or suggest each and every element of the claims. Claims 12-15, 17 and 18, dependent on claim 11, and claims 20-23, 25 and 26, dependent on claim 19, are thus also not anticipated. Accordingly, claims 11-15, 17-19, 21-23, 25 and 26 are not anticipated by Hevey et al., and Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 USC § 103

Claims 13, 16, 20 and 24 were rejected under 35 USC § 103(a) as being obvious over Hevey et al. (U.S. Patent No. 4,228,237) in view of Huber et al. (U.S. Patent No. 5,219,764). For claims 13 and 20, the Examiner asserted that it is well

known to use identical haptens or their derivatives in competition assays. For claims 16 and 24, the Examiner asserted that it would have been obvious to combine the sandwich assay of Hevey et al. with the homogeneous assay methods of Huber et al. The rejection of claims 16 and 24 is moot, as these claims have now been cancelled.

The rejection of the claims under 35 U.S.C. § 103(a) is respectfully traversed. The Examiner has not established a *prima facie* case of obviousness as the applied references, alone or in combination, fail to provide each and every element of the claims. In particular, the references do not teach or suggest Applicants' ingredient (c); that is, an assay component comprising a binding partner that binds both the 1st hapten or hapten-like molecule and the 2nd hapten or hapten-like molecule without interacting with the analyte. Independent claims 11 and 19, from which pending claims 13 and 20 depend, each include ingredient (c), a binding partner that binds both the 1st hapten or hapten-like molecule and the 2nd hapten or hapten-like molecule without interacting with the analyte.

As noted above, Hevey et al. does not teach or suggest an assay component comprising a binding partner that binds both the 1st hapten or hapten-like molecule and the 2nd hapten or hapten-like molecule without interacting with the analyte. Likewise, Huber et al. does not teach or suggest, nor has the Examiner asserted that Huber et al. teaches or suggests, an assay component comprising a binding partner that binds both the 1st hapten or hapten-like molecule and the 2nd hapten or hapten-like molecule without interacting with the analyte. Thus, the combination of Hevey et al. and Huber et al., even if proper,

does not teach the claimed assay component, nor is there any suggestion in the references alone or in combination, to provide the claimed assay component.

The Examiner's statement regarding the well known use of identical haptens or their derivatives is insufficient to provide a *prima facie* of obviousness, since this statement does not provide a teaching or suggestion to provide an assay component as recited in the claims. Accordingly, claims 13 and 20 are not obvious over Hevey et al. or Huber et al., alone or in combination.

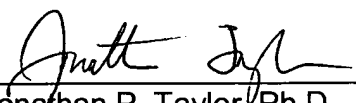
CONCLUSION

In conclusion, all of the grounds raised in the present Office Action for rejecting the application are believed to be overcome or rendered moot based on the amendments and remarks above. Thus, it is respectfully submitted that all of the presently presented claims are in condition for allowance. Should the Examiner feel a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact the undersigned.

Respectfully submitted,

Dated:

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